

REMARKS

Claims 125, 126 and 128-144 were pending in the present application. Applicants have canceled claim 126 without prejudice. Such a cancellation does not raise any issue of new matter. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 125 and 128-144 will be under examination.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 125, 126 and 128-145 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement insofar as the claimed pharmaceutical dosage form reads on an aqueous composition.

Applicants respectfully point out that the azithromycin in the claimed pharmaceutical dosage form is crystalline (emphasis added) azithromycin monohydrate hemi-ethanol solvate and therefore, the claims cannot be interpreted to cover pharmaceutical dosage forms where azithromycin monohydrate hemi-ethanol solvate is dissolved into a solution and lose its crystal structure. Applicants note that the present response will form part of the prosecution history for the present application and the statements in the present Amendment will be used to aid the proper interpretation the scope of the claims. With such a clear and unambiguous statement from Applicants on the scope of the claims, the currently pending claims can only be interpreted as not covering a solution of azithromycin monohydrate hemi-ethanol solvate. Therefore, this ground of rejection is moot as the full scope of the pending claims, as properly interpreted, are fully enabled.

REJECTION UNDER 35 U.S.C. §102(b) & §103(a)

Claims 125, 126 and 128-145 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bright, U.S. Patent No. 4,474,768 (hereinafter "Bright").

Applicants respectfully disagree with this ground of rejection for the same reasons as stated in Applicants' response to the rejection under 35 U.S.C. §112, first paragraph.

Applicants respectfully submit that the currently pending claims, when properly construed in view of the file history which includes the present Amendment, would not cover pharmaceutical dosage forms where the substantially pure azithromycin monohydrate hemi-ethanol solvate is dissolved into a solution and lose its crystal structure. Therefore, this ground of rejection is moot. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

REJECTION UNDER 35 U.S.C. §103(a)

Claims 126-145 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Singer et al., U.S. Patent No. 6,365,574 (hereinafter “Singer”) in view of Curatolo et al., U.S. Patent No. 5,605,889 (hereinafter “Curatolo”).

Applicants note that the obviousness rejection of claims 126-145 is over the combination of Singer and Curatolo. Neither Singer nor Curatolo, as an individual reference, would not render any of the pending claims obvious.

Applicants would like to point out that Singer is not a proper reference against the present application. Applicants further note that Singer has a publication date of April 2, 2002 and present application has an earliest priority date of May 22, 2001, i.e., the filing date of U.S. Provisional Application No. 60/292,565.

In addition, as shown in the July 13, 2005 declaration from Dr. Todd Darrington (attached herein), Applicants had reduced the claimed invention to practice prior to May 8, 1998, before the April 2, 2002 publication date of Singer. Therefore, this ground of rejection is moot. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CONCLUSION

In view of the claim amendments and the remarks, further and favorable considerations of the presently pending claims are respectfully requested.

It is believed that no fee is required in connection with the present Amendment. However, if any fees are required, the Commissioner is authorized to charge such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

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